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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,449	03/24/2004	Karin Jooss	3802-090-27 CIP	3354
29585	7590	06/22/2007		
DLA PIPER US LLP 153 TOWNSEND STREET SUITE 800 SAN FRANCISCO, CA 94107-1957			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
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			06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/807,449	Applicant(s) JOOSS ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,9, 12 - 18, 21 - 22, 25 and 27 - 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 2, 4, 6 - 8, 10 - 11, 19 - 20, 23 - 24, and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTC-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/2/04; 12/8/04; 3/13/06</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Applicant's amendment/remarks, filed on 04/12/2007, are acknowledged.

**Claims 1 – 43 are pending.**

Claims 12 – 18, 21 – 22, 25, and 27 – 43 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 11/21/2006.

2. Applicant's election of the Species allogeneic cells and prostate cancer in the reply filed on 04/12/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 5, and 9 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

***Claims 1 – 2, 4, 6 – 8, 10 – 11, 19 – 20, 23 – 24, and 26 are under consideration in the instant application, as they read on the elected invention and species.***

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3. Claims 1 – 2, 4, 6 – 8, 10 – 11, 19 – 20, 23 – 24, and 26 are objected to as reading on non-elected embodiments of the invention, which are not under consideration in the instant application. Applicant is required to cancel the non-elected embodiments.

4. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

5. Claims 1 – 2, 4, 6 – 8, 10 – 11, 19 – 20, 23 – 24, and 26 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

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The specification does not provide a sufficient enabling description of a method for cancer therapy comprising administering a cellular vaccine.

The National Cancer Institute, in a Cancer Vaccine Fact Sheet (updated 06/08/2006; see entire document) states that "there are no licensed therapeutic vaccines to date" (section 2 at page 2). Therefore, it would take undue trial and error to practice the claimed invention.

6. Claim 1 is rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of a generically recited "cytokine-expressing cellular vaccine."

The instant specification discloses one example of a cytokine-expressing cellular vaccine, in particular a vaccine expressing CM-CSF (e.g. page 12). However, one of skill in the art is aware of a plurality of cytokines which differ in their structures, functions, and mechanisms of action. Applicant has not disclosed sufficiently detailed, relevant identifying characteristics, e.g. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, to demonstrate possession of the recited genus. Given the limited written description in the instant specification, the skilled artisan cannot envision all the contemplated structural possibilities encompassed by the instant claims. See Guidelines, 66 Fed. Reg. at 1106.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

7. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

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8. Claims 1 – 2, 4, 6 – 7, 11, 19 – 20, 23 – 24, and 26 are rejected under **35 U.S.C. 102(a)** as being anticipated by Gri et al. (J. Immunol., 2003 (January), 170: 99 – 106; see entire document).

Gri et al. teach a method of treating colon carcinoma by administering carcinoma cells transduced to express GM-CSF and OX40 ligand (e.g. Results at page 101). Gri et al. further teach that OX40 ligand is functionally equivalent with anti-OX40 antibodies (e.g. page 105, last paragraph of Discussion). Thus a method of treating cancer by administering GM-CSF-expressing cells and anti-OX40 antibodies is inherent in the teachings of Gri et al. The reference further teaches that the GM-CSF-expressing cells are inactivated by irradiation (e.g. page 100, last full paragraph), and envisions using the method for human therapy (e.g. pages 99 – 100, bridging paragraph).

Therefore, the reference teachings anticipate the instant claimed invention.

9. Claims 1 – 2, 4, 6 – 8, 10 – 11, 19 – 20, 23 – 24, and 26 are rejected under **35 U.S.C. 102(a) and 102(e)** as being anticipated by Chen et al. (US Pat. Pub. No. 2003/0035790; see entire document).

Chen et al. teach a method of treating cancer by administering a recombinant adenovirus engineered to express GM-CSF, and an anti-OX40 antibody (e.g. paragraphs 00341, 0117, 0120, and 0277). Chen et al. further teach GM-CSF may be expressed in mammalian cells (e.g. paragraphs 0212 – 0214), and discuss a cancer vaccine approach, wherein cancer cells are isolated from patients, transduced in vitro, irradiated, and administered to patients (e.g. paragraph 0005). In view of these teachings, one of skill in the art would immediately envisage a method wherein the GM-CSF-expressing cells are administered, along with anti-OX40 antibodies, to treat cancer. Chen et al. also teach that these methods can be applied to treating prostate cancer (e.g. claim 39).

Therefore, the reference teachings anticipate the instant claimed invention.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



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11. Claims 1 – 2, 4, 6 – 8, 10 – 11, 19 – 20, 23 – 24, and 26 are provisionally rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 1 – 33 of copending Application USSN 10/404,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1 – 2, 4, 6 – 8, 10 – 11, 19 – 20, 23 – 24, and 26 are directed to an invention not patentably distinct from claims 1 – 33 of commonly assigned USSN 10/404,662, for the reasons addressed supra.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USSN 10/404,662, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

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**13. Conclusion: no claim is allowed.**

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "Ilia Ouspenski". The signature is written in a cursive, flowing style with a large initial "I" and "O".

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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June 18, 2007